REMARKS

In view of the comments which follow, reconsideration of the Official Action of July 2, 2003 is respectfully requested by Applicants.

A current Claims Listing (2 pages) is submitted herewith.

Claims 44-52 are pending and stand finally rejected. Claims 53-69 have been canceled since they belong to a non-elected invention group.

Rejection under 35 USC §102 (b)

In Paragraph 4 of the instant action, claims 44, 47-49, 51, and 52 have been rejected under 35 USC §102 (b) as being anticipated by Kuo, EP 813,064 A1 (hereinafter "Kuo"). The Examiner argues that Kuo discloses *a solid support on which an antibody specific to an epitope of an analyte and a first labeled antibody, which is specific to another epitope of the analyte, are immobilized.* A second labeled antibody is also provided which is specific to the first labeled antibody (abstract). The signal generated by the complex is detected on the substrate. According to one embodiment, there is a reagent region containing a second antibody labeled with gold sol, a second reagent region containing a third antibody labeled with gold sol, and a capture zone with immobilized first antibody (column 4). The support may also be provided with a positive control zone (column 5).

Applicants argue that the Examiner's understanding of the number of antibodies immobilized on the solid support is in error (see italicized passage in previous paragraph). Kuo does not teach a solid support comprising a first and a second spatially separate test area, a first receptor bound to the first test area, and a second receptor bound to the second test area as recited in Applicants claims 44, 47-49, 51, and 52. Rather, Kuo teaches a single test area ("capture zone") and a single receptor bound ("immobilized") to that test area. The paragraph bridging columns 4 and 5, as well as Figure 2, teach a

nitrocellulose test strip (10) having a wicking pad (1), a reagent region (3) containing Ab2, a second reagent region (5) containing Ab3, and a capture zone (7) in which there is immobilized Ab1. Test fluid is applied to the wicking pad where it is absorbed and begins its flow up the strip through zones 3 and 5 and eventually to detection zone 7 where the detectable signal from the signal generator is observed. Ab2 and Ab3 cannot be bound or immobilized to the reagent regions, otherwise the test described by Kuo would not be operable. Kuo does describe an optional embodiment having a positive control zone (9) containing an immobilized specific binding partner for either labeled Ab2 or Ab3. This binding partner, however, does not bind specifically with the analyte as required in Applicants' claimed invention. Kuo teaches that the only analyte-specific antibody is bound to the solid phase. A second, analyte-specific antibody bound to a separate test area is not taught or suggested by Kuo.

APPLICANT'S IS WRONG

Since Kuo does not teach a solid support comprising a first and a second spatially separate test area nor a first receptor specific for an analyte and bound to a first test area and a second receptor specific for the analyte and bound to a second test area, Kuo cannot anticipate Applicants' invention. Applicants respectfully request the Examiner's reconsideration of his rejection of claims 44, 47-49, 51, and 52.

In Paragraph 5 of the instant action, claims 44, 45, 49, and 51 have been rejected under 35 USC §102 (b) as being anticipated by Bellet et al., U.S. Patent No. 5,011,771 (hereinafter "Bellet"). The Examiner argues that Bellet discloses an immunometric assay comprising the formation of a complex between antigen and multiple immobilized monoclonal antibodies against different epitopes of the antigen and with a detectably labeled monoclonal antibody. According to the reference, the Examiner argues, it is important that the multiple immobilized antibodies be bound in close proximity (column 8, lines 7-9).

Applicants argue that Bellet does not disclose first and second spatially separate test areas as recited in Applicants' claims. Furthermore, Bellet does not disclose a first

receptor bound to a first test area and a second receptor bound to a second test area, there being no more than one analyte-specific receptor bound per test area as recited in Applicants' claims. As the Examiner points out, Bellet teaches at column 8, lines 7-9, "It is important that the multiple immobilized antibodies be bound to the same solid phase since close proximity is important." However, in the next sentence, Bellet explains, "This can be readily achieved by either simultaneous or sequential binding of each antibody on the same solid phase." In Example 1, column 11, lines 57-64, Bellet teaches "Systematic testing of different combinations of monoclonal anti-AFP demonstrated that the most sensitive assay for serum AFP determination was a simultaneous sandwich monoclonal RIA based on a mixture of AF01 and AF03 as bound antibodies on the solid phase support and AF01 as the radiolabelled indicator antibody." In other words, Bellet teaches a mixture of more than one antibody applied to the solid phase. Spatially separate test areas with no more than one analyte-specific receptor bound per test area are not only not taught by Bellet, they are taught away from by Bellet.

Since Bellet does not teach a solid support comprising a first and a second spatially separate test area nor a first receptor bound to the first test area and a second receptor bound to the second test area, there being no more than one analyte-specific receptor bound per test area, Bellet cannot anticipate Applicants' invention. Applicants respectfully request the Examiner's reconsideration of his rejection of claims 44, 45, 49, and 51.

Rejections under 35 USC §103 (a)

In Paragraph 9 of the instant action, claims 45, 46, and 50 have been rejected under 35 USC §103 (a) as being unpatentable over Kuo, EP 813,064 A1 (hereinafter "Kuo"). The Examiner argues that the reference teaches an immunoassay method as previously discussed under 35 USC §102 (b). However, the reference does not teach specific analytes or the size of the test area. The Examiner argues that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use

test areas with diameters less than 1 mm and assay for specific analytes with the method and kit of Kuo.

In rebuttal, Applicants argue that the Examiner's case for *prima facie* obviousness has not been made. Claims 45, 46, and 50 depend from independent claims 44 and 49, respectively. Patentability of claims 44 and 49 has been argued under 35 USC §102 above, and dependent claims 45, 46, and 50 should enjoy the same patentability as the claims from which they depend. Applicants respectfully request the Examiner's reconsideration of this grounds for rejection of claims 45, 46, and 50.

In paragraph 10 of the instant action, claims 46-48, 50, and 52 have been rejected under 35 USC §103 (a) as being unpatentable over Bellet et al., U.S. Patent No. 5,011,771 (hereinafter "Bellet"). The Examiner argues that the reference teaches a multiepitopic assay as previously discussed under 35 USC §102 (b). However, the reference does not teach the diameter of the test area, a control area, or latex particles as the label. The Examiner argues that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a control area and latex particles as the label with the method and kit of Bellet.

In rebuttal, Applicants argue that the Examiner's case for *prima facie* obviousness has not been made. Claims 46-48, 50, and 52 depend from independent claims 44, 49, and 51, respectively. Patentability of claims 44, 49, and 51 has been argued under 35 USC §102 above, and dependent claims 46-48, 50, and 52 should enjoy the same patentability as the claims from which they depend. Applicants respectfully request the Examiner's reconsideration of this grounds for rejection of claims 46-48, 50, and 52.

Applicants submit that their application is now in condition for allowance, and favorable reconsideration of their application in light of the above amendments and remarks is respectfully requested. Allowance of claims 44-52 at an early date is earnestly solicited.

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The Examiner is hereby authorized to charge any fees associated with this Amendment to Deposit Account No. 50-0877. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Marilyn Amick

Marilyn L. Amick
Reg. No. 30,444

Roche Diagnostics Corp.
9115 Hague Road
Indianapolis, IN 46250
Phone: 317-521-7561
Fax: 317-521-2883